IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:20-CV-522-FL

NORTH CAROLINA INSURANCE GUARANTY ASSOCIATION, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and CENTER FOR MEDICARE AND MEDICAID SERVICES, Defendants.[1]	)	ORDER

This case wherein plaintiff seeks judicial declaration of its responsibilities under the federal Medicare statutory scheme and challenges defendants' administrative determination regarding the same is before the court on defendants' motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and (6) (DE 9). The motion has been briefed fully, and the issues raised are ripe for ruling. For the following reasons, defendants' motion is granted.

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1 The court has modified of its own initiative the case caption to reflect substitution of former-defendant Alex M. Azar II in his official capacity, where he "cease[d] to hold office while the action [was] pending," and "[t]he officer's successor," Xavier Becerra, "is automatically substituted as a party." Fed. R. Civ. P. 25(d). Accordingly, the clerk shall conform the docket to reflect substitution of this defendant.

STATEMENT OF THE CASE

Plaintiff commenced this action on October 5, 2020, seeking a declaration, pursuant to 28 U.S.C. § 2201, that it is not a "primary plan" or an "applicable plan" under the Medicare Secondary Payer ("MSP") statute, 42 U.S.C. § 1395y(b). Plaintiff also alleges that defendants have violated the Administrative Procedures Act, 5 U.S.C. § 706, and the standards enumerated in 42 U.S.C. § 405(g), as applicable to the Secretary of the United States Department of Health and Human Services ("the Secretary") under 42 U.S.C. § 1395ii, through their determination regarding plaintiff's MSP responsibilities. Plaintiff seeks this judicial declaration along with injunctive relief against defendants preventing them from enforcing certain MSP-reporting requirements against plaintiff.

STATEMENT OF THE FACTS

The facts alleged in the complaint may be summarized as follows. Plaintiff as a statutorily created association, N.C. Gen. Stat. § 58-48-25, consists of insurers admitted to conduct insurance business in North Carolina and to write insurance pursuant to the Insurance Guaranty Association Act ("the Act"), N.C. Gen. Stat. § 58-48-1. Plaintiff was created in order "to establish a fund from which insureds and claimants could obtain limited statutory benefits in the event a member insurer became" insolvent. (Compl. ¶ 11). Plaintiff is obligated statutorily to "pay[] certain defined 'covered claim[s]' arising out on an insurance policy of an insolvent insurer." (Id.). It funds payment, adjustment, and defense of covered claims by assessing its members, who recoup this cost through a tax offset.

However, according to the complaint, plaintiff does not issue insurance policies, collect premiums, make profits, or assume contractual obligations to the insureds of insolvent insurers. It "does not and cannot 'stand in the shoes' of the insolvent insurer for all purposes." (Id. ¶ 18).

Plaintiff is only obligated in regard to a "covered claim[]," which is "not co-extensive with the insolvent insurer's obligations under its policies," (id.), and which is statutorily defined as

> an unpaid claim . . . which is in excess of fifty dollars . . . and arises out of and is within the coverage . . . of an insurance policy to which [the Act] applies . . . if such insurer becomes an insolvent insurer . . . and (i) the claimant or insured is a resident of this State at the time of the insured event; or (ii) the property from which the claim arises is permanently located in this State.

(Id. ¶ 17 (quoting N.C. Gen. Stat. § 58-48-20(4))). A covered claim does not include

> any amount awarded (i) as punitive or exemplary damages; (ii) sought as a return of premium under a retrospective rating plan; or (iii) due any reinsurer, insurer, insurance pool, or underwriting association, as subrogation or contribution recoveries or otherwise.

(Id. (quoting N.C. Gen. Stat. § 58-48-20(4))).

Historically, defendants have treated plaintiff as a "primary plan" under the MSP statute because certain Medicare beneficiaries are, and were, also claimants under policies issued by insolvent insurers, making those claimants eligible for payments of covered claims. (Compl. ¶¶ 26-27). This required plaintiff, under the MSP statute, to pay defendants for certain conditional payments defendants made with regard to those claimants.

On June 1, 2020, plaintiff sought a written opinion from defendant Center for Medicare and Medicaid Services ("Center") to the effect that it was not a primary plan and did not fall under the MSP statute's reporting requirements, relying on the United States Court of Appeals for the Ninth Circuit's decision in California Insurance Guarantee Association v. Azar, 940 F.3d 1061 (9th Cir. 2019) (hereinafter CIGA). Defendants Center and United States Department of Health and Human Services ("Department") replied by August 12, 2020, letter denying the request for a written opinion, asserting, in part, that the Ninth Circuit's opinion was inapplicable to plaintiff. In contrast, defendants Department and Center had confirmed by written opinion letter, dated May

21, 2020, to the California Insurance Guarantee Association that the organization was no longer required to comply with the MSP statute's reporting requirements.

COURT'S DISCUSSION

A. Motion to Dismiss

1. Standard of Review

A motion to dismiss under Rule 12(b)(1) challenges the court's subject matter jurisdiction. Such motion may either 1) assert the complaint fails to state facts upon which subject matter jurisdiction may be based, or 2) attack the existence of subject matter jurisdiction in fact, apart from the complaint. Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982). When a defendant challenges the factual predicate of subject matter jurisdiction, a court "is to regard the pleadings' allegations as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." Richmond, Fredericksburg & Potomac R.R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991). The nonmoving party in such case "must set forth specific facts beyond the pleadings to show that a genuine issue of material fact exists." Id. On the other hand, where a defendant raises a "facial challenge[] to standing that do[es] not dispute the jurisdictional facts alleged in the complaint," the court accepts "the facts of the complaint as true as [the court] would in context of a Rule 12(b)(6) challenge." Kenny v. Wilson, 885 F.3d 280, 287 (4th Cir. 2018).

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. In evaluating whether a claim is stated, "[the] court accepts all well-

pled facts as true and construes these facts in the light most favorable to the plaintiff," but does not consider "legal conclusions, elements of a cause of action, . . . bare assertions devoid of further factual enhancement[,] . . . unwarranted inferences, unreasonable conclusions, or arguments." Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009) (quotations omitted).

2. Analysis

a. The MSP Statute

As a preliminary matter, the court summarizes the relevant MSP statutory scheme. Section 1395y provides that the Medicare Trust Fund is a "secondary payer," that is, Medicare is not primarily responsible for payment,[2] for certain otherwise covered items and services where "payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance." 42 U.S.C. 1395y(b)(2)(A).

However, § 1395y allows the Secretary to make conditional payments "if a primary plan . . . has not made or cannot reasonably be expected to make payment with respect to . . . [a covered] item or service promptly." Id. § 1395y(b)(2)(B)(i); Netro, 891 F.3d at 524 ("Where a private party responsible for medical costs does not or cannot promptly meet its obligations, Medicare may pay up front, so long as the responsible party eventually reimburses the government."). This payment is "conditioned on reimbursement to the appropriate Trust Fund," 42 U.S.C. § 1395y(b)(2)(B)(i),

[2] As 42 C.F.R. § 411.21 explains, "secondary, when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other coverage that is primary to Medicare." See also Netro v. Greater Baltimore Med. Ctr., Inc., 891 F.3d 522, 524 (4th Cir. 2018) (explaining that the MSP statute "inverted th[e prior] system and made Medicare an entitlement of last resort, available only if no private party was liable" (quotation omitted)).

which is required "if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service." Id. § 1395y(b)(2)(B)(ii). The statute defines a "primary plan" as "a group health plan or large group health plan, . . . a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance." Id. § 1395y(b)(2)(A)(ii); 42 C.F.R. § 411.21.

Section 1395y also requires that "applicable" liability insurance, no fault insurance, and workers' compensation "plans," meaning, in effect, "primary plans," submit periodic reports regarding determinations of whether claimants are entitled to receive benefits under Medicare. See 42 U.S.C. § 1395y(b)(8)(A)-(B), (F). Failure to comply with this reporting requirement may result in "a civil penalty of up to $1,000 for each day of noncompliance with respect to each claimant," which is "in addition to any Medicare secondary payer claim" with respect to that claimant, if required. See id. § 1395y(b)(8)(E).[3]

As to administrative and judicial review, the Medicare Act provides that the "Secretary shall . . . make initial determinations with respect to benefits . . . including an initial determination by the Secretary that payment may not be made, or may no longer be made." 42 U.S.C. § 1395ff(a)(1). The relevant regulations explain that an "initial determination . . . includes . . . determinations . . . [u]nder the Medicare Secondary Payer provisions . . . that Medicare has a recovery claim if Medicare is pursuing recovery directly from an applicable plan." 42 C.F.R. § 405.924(b)(16). "An individual dissatisfied with any initial determination . . . shall be entitled to . . . a hearing thereon by the Secretary to the same extent as provided in [42 U.S.C. § 405(b)] and

[3] The rulemaking, regarding the discretionary imposition of such civil money penalties, directed by statute, 42 U.S.C. 1395y(b)(8)(I), is ongoing. See Medicare Program; Medicare Secondary Payer and Certain Civil Money Penalties, 85 Fed. Reg. 8793 (proposed Feb. 18, 2020) (to be codified at 42 C.F.R. pt. 402 & 45 C.F.R. pt. 102).

. . . to judicial review of the Secretary's final decision after such hearing as is provided in [42 U.S.C. § 405(g)]." 42 U.S.C. § 1395ff(b)(1)(A).

Although the rule is still in the process of being finalized, defendants similarly state that when the regulations implementing 42 U.S.C. § 1395y(b)(8)(E)'s discretionary civil money penalty for non-reporting are finalized, they "expect that [the] proposed rule . . . would comport with the appeals process as prescribed by 42 C.F.R. 402.19 and set forth under 42 CFR part 1005." See Medicare Program; Medicare Secondary Payer and Certain Civil Money Penalties, 85 Fed. Reg. 8793, 8793-94 (proposed Feb. 18, 2020) (hereinafter "Proposed CMP Rule"). Section 402.19 guides that "[t]he hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination" such as "a civil money penalty." Part 1005 prescribes an initial hearing before an administrative law judge ("ALJ") upon request after a sanction, like a civil money penalty. See 42 C.F.R. § 1005.2. The ALJ's decision on the sanction may be appealed to the Departmental Appeals Board ("DAB"), which may "decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty . . . determined by the ALJ." See id. § 1005.21. After such, the decision becomes final and judicial review may be sought under the auspices of 42 U.S.C. § 1320A-7A(e). See id. § 1003.1450. Section 1320A-7A(e) permits review of such determinations by "the United States Court of Appeals for the circuit in which the person resides, or in which the claim or specified claim was presented." Id. § 1320A-7A(e). Once the record is filed with the relevant court of appeals, its jurisdiction "shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States." Id.

b. Subject Matter Jurisdiction

i. Constitutional Requirements

Two of Article III's requirements for federal jurisdiction, which only extends to resolution of cases and controversies, are implicated here. First is the constitutional requirement of standing, that is, that "plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." Friends of the Earth, Inc. v. Gaston Copper Recycling Corp., 204 F.3d 149, 154 (4th Cir. 2000) (internal quotation marks omitted) (quoting Allen v. Wright, 468 U.S. 737, 751 (1984)). Second, the complaint raises concerns regarding the concept of ripeness, which requires that "a controversy is presented in 'clean-cut and concrete form'" before "judicial consideration of issues." Miller v. Brown, 462 F.3d 312, 318-19 (4th Cir. 2006) (quoting Rescue Army v. Mun. Court of L.A., 331 U.S. 549, 584 (1947)).

The court turns its attention to plaintiff's standing to sue. "The party invoking federal jurisdiction bears the burden of establishing standing." Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158, (2014) (quotation omitted); see also Kenny, 885 F.3d at 287 ("At least one plaintiff must demonstrate standing for each claim and form of requested relief."). "[A] party invoking the jurisdiction of a federal court [must] seek relief for a personal, particularized injury." See Hollingsworth v. Perry, 570 U.S. 693, 715 (2013); Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992) ("[P]laintiff must have suffered . . . an invasion of a legally protected interest which is . . . concrete and particularized . . . ."). Additionally, the alleged injury must be "actual or imminent, not conjectural or hypothetical." Lujan, 504 U.S. at 560 (quotation omitted).

"An allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." Susan B. Anthony List, 573 U.S. at 158

(quotation omitted). "[A]llegations of possible future injury are not sufficient." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 409 (2013) (quotation omitted). When there is the threat of the "enforcement of a law," "an actual . . . enforcement action is not a prerequisite to challenging the law." Susan B. Anthony List, 573 U.S. at 158. Rather, "pre-enforcement review" is "permitted . . . under circumstances that render the threatened enforcement sufficiently imminent." Id. at 159. This means that the threat must be "credible" and the fear of enforcement more than "imaginary or speculative." Babbitt v. United Farm Workers, 442 U.S. 289, 298 (1979); cf. Doe v. Duling, 782 F.2d 1202, 1206 (4th Cir. 1986) ("A litigant must show more than the fact that state officials stand ready to perform their general duty to enforce laws.").

Here, plaintiff's complaint reveals three potential injuries: (1) potential repayments to defendants under § 1395y(b)(2)(B); (2) potential civil penalties levied against plaintiff if it fails to engage in the reporting required by § 1395y(b)(8); and (3) incurring certain burdens and expenses related to the statutory scheme. The first two are too speculative to constitute injury-in-fact, as discussed below, and the third is not supported by sufficient factual allegations in the complaint.

First, it is inferable from the complaint that, due to defendants' allegedly incorrect position that plaintiff is a primary plan, plaintiff may be "required as a 'primary plan' under the MSP [statute] to repay [d]efendants for any 'conditional' payments made by [d]efendants to someone who ultimately is determined to be due statutory benefits for a 'covered claim' under" the statute enshrining plaintiff's responsibilities. (See Compl. ¶¶ 26-27). However, plaintiff concedes that "no conditional payment is presently sought." (Pl.'s Resp. (DE 13) at 18). This theory of injury is impermissibly premised on a "speculative chain of possibilities," see Clapper, 568 at 410 (construing Summers v. Earth Island Inst., 555 U.S. 488, 496 (2009)): that is, that an individual will at some point possibly bring a claim, covered by Medicare, that constitutes a "covered claim"

for the purposes of N.C. Gen. Stat. § 58-48-20, which plaintiff should have paid for but did not and for which defendants made a conditional payment that they now seek to recoup from plaintiff. This is too speculative to constitute the concrete injury required by Article III.

Next, plaintiff complains of "substantial potential penalties for failing to comply with" § 1395y(b)(8)'s reporting requirements. (See Compl. ¶ 25). However, again, plaintiff concedes that "no penalties have been imposed," (Pl.'s Resp. (DE 13) at 18), and, instead, bases its injury on the "untenable" "uncertainty surrounding whether [plaintiff] is or is not subject to [§ 1395y(b)(8)] reporting." (Compl. ¶ 34). Yet, as defendants point out, administrative rulemaking is ongoing to establish the regulatory standards for when civil penalties will and will not be imposed. See Proposed CMP Rule, 85 Fed. Reg. at 8793-94. This is as directed by statute, 42 U.S.C. § 1395y(b)(8)(I), which imagines that "[a]n applicable plan . . . may be subject to a civil money penalty, id. § 1395y(b)(8)(E) (emphasis added). Defendants' rule, while not yet final, would only impose civil money penalties "on a prospective basis." Proposed CMP Rule, 85 Fed. Reg. at 8796.

Plaintiff's mere speculation that it will be civilly penalized is insufficient to demonstrate that the threatened injury is certainly impending, and its conjecture and mere uncertainty do not establish substantial risk that the harm will occur. Defendants' letter denying plaintiff's request for a written opinion and incidentally stating that it did not agree that the Ninth Circuit's opinion in CIGA was applicable to plaintiff does not constitute the requisite credible threat of sufficiently imminent enforcement of civil money penalties against plaintiff.

Finally, the court considers plaintiff's allegation of incurring expenses and costs as past and present injury. Plaintiff asserts in its response to the instant motion that it has incurred "burdens and expenses . . . in complying with the [§ 1395y(b)(8)] quarterly reporting obligations

of the MSP [statute].” (Pl.’s Resp. (De 13) at 20). The United States Court of Appeals for the Fourth Circuit has recognized that the demonstration by a plaintiff “that it will incur costs . . . so that it may avoid violation” of a challenged provision supports standing to challenge that provision in certain contexts. See Chambers Med. Techs. of S.C., Inc. v. Bryant, 52 F.3d 1252, 1255 (4th Cir. 1995); see also EQT Prod. Co. v. Wender, 870 F.3d 322, 331 (4th Cir. 2017) (“EQT would be required to shift its permanent wastewater disposal operations out of Fayette County, and it is undisputed that such a change would impose additional costs on EQT. That is enough to give rise to an Article III injury in fact.”).

Even assuming that Chambers’s rationale is applicable to plaintiff’s alleged “expenses and costs,” plaintiff has not tied these to compliance activities to avoid violation of the reporting statute. Rather, under plaintiff’s claim pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, the complaint states, without further factual elaboration, “[t]he acts alleged herein by [defendants] were performed in an official capacity . . . which has caused [plaintiff] to suffer a legal wrong, and incur burdens and expenses never contemplated or provided for in the Guaranty Act.” (Compl. ¶ 39). At this stage of litigation, “each element [of standing],” including injury-in-fact, “must be supported in the same way as any other matter on which the plaintiff bears the burden of proof,” Lujan, 504 U.S. at 561, which, here, requires more than bare assertions devoid of further factual enhancement that leave to speculation which, if any, of defendant’s purportedly illegal acts caused plaintiff’s expenses and costs. Cf. Crane v. Johnson, 783 F.3d 244, 252 (5th Cir. 2015) (affirming district court’s holding that state-plaintiff’s “alleged fiscal injury was purely speculative because there was no concrete evidence that [state-plaintiff’s] costs had increased or will increase as a result of” the challenged statute and concluding that plaintiff-state “was required to demonstrate that the state will incur costs because of the” challenged statute).

In sum, concluding that plaintiff has shown injury-in-fact would contravene the "longstanding legal doctrine preventing [courts] from providing advisory opinions at the request of one who, without other concrete injury, believes that the government is not following the law." See Carney v. Adams, 141 S.Ct. 493, 501 (2020). While plaintiff very well may later be subject to a more sufficient threat of civil money penalties or threat of recoupment action, those injuries are too speculative to ground plaintiff's claim today. Nor has plaintiff alleged a sufficient factual basis for the court to find that its ostensibly incurred costs and expenses stemmed from attempts to comply with § 1395y(b)(8) reporting requirements that it asserts the court should declare do not apply to it.

On related grounds, as implied above, plaintiff's claim is not yet ripe. "The burden of proving ripeness falls on the party bringing suit." Miller, 462 F.3d at 319. "To determine whether the case is ripe, [the court] balance[s] the fitness of the issues for judicial decision with the hardship to the parties of withholding court consideration." Id. (quotation omitted). "A case is fit for judicial decision . . . when the action in controversy is final and not dependent on future uncertainties." Id. "The hardship prong is measured by the immediacy of the threat and the burden imposed on the [plaintiffs] who would be compelled to act under threat of enforcement of the challenged law." Charter Fed. Sav. Bank v. Off. of Thrift Supervision, 976 F.2d 203, 208-09 (4th Cir. 1992). "The purpose of the ripeness doctrine is 'to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way . . . .'" South Carolina v. United States, 912 F.3d 720, 730 (4th Cir. 2019) (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967)).

Here, for similar reasons that plaintiff's injuries are too speculative at this juncture, its claims are not yet ripe. See generally Miller, 462 F.3d at 319, ("Analyzing ripeness is similar to determining whether a party has standing."). No action has finalized beyond defendants' refusal to render a written opinion, and the imposition of fines or repayment obligations is dependent on future uncertainties. See Texas v. United States, 523 U.S. 296, 300 (1998) ("[W]here '[the court] ha[s] no idea whether or when such [a sanction] will be ordered,' the issue is not fit for adjudication." (fourth alteration in original) (quoting Toilet Goods Assn., Inc. v. Gardner, 387 U.S. 158, 163 (1967))). Further, plaintiff has not shown an immediacy of any threat, e.g., a pending enforcement action or sufficiently concrete threat of enforcement. Nor, as noted above, has it demonstrated sufficiently the burden imposed upon it due to feeling compelled to act under possible threat of enforcement of the challenged law. Ripeness as a doctrine seeks to prevent the very type of action plaintiff purports to bring, one that would entangle the court in the parties' abstract disagreement over potential repayments and civil penalties for reporting requirements, upon which defendant Department has not yet formalized an administrative decision and which plaintiff has not demonstrated it has felt in a concrete way.

This court only has Article III jurisdiction over actual cases or controversies, which the underlying action has not been demonstrated to be. Accordingly, plaintiff's complaint is dismissed without prejudice due to lack of jurisdiction.

ii. Statutory Bases

In the alternative, plaintiff has not shown that its alleged statutory jurisdictional bases are proper. Plaintiff's complaint invokes the court's original subject matter jurisdiction pursuant to 5

U.S.C. § 702, 28 U.S.C. § 1331, 42 U.S.C. §§ 405(g), 1395ii & 1395y(b).[4] The court addresses each in turn.

1) The Administrative Procedures Act

Section 702 of Title 5 of United States Code waives "the federal government's sovereign immunity," a concept that is "jurisdictional in nature," for suits "brought by 'a person suffering legal wrong because of agency action' to obtain relief 'other than money damages.'" City of New York v. U.S. Dep't of Def., 913 F.3d 423, 430 (4th Cir. 2019) (quoting 5 U.S.C. § 702). An "'agency action' includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof." 5 U.S.C. § 551(13); see also id. § 701(2) ("'[A]gency action' ha[s] the meaning[] given [it] by section 551 . . . ."). Further, the agency action must either be "made reviewable by statute" or a "final agency action for which there is no other adequate remedy in a court." Id. § 704.

To constitute final agency action, "the action must mark the 'consummation" of the agency's decisionmaking process . . . and . . . the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Bennett v. Spear, 520 U.S. 154, 178 (1997) (first quoting Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948); and then quoting Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)).

Here, plaintiff does not allege that defendants' August 12, 2020, letter constitutes final agency action under this definition nor does review of the letter, as attached to the complaint, see

[4] Although plaintiff asserts a claim pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, "a claim under the Declaratory Judgment Act, even if made, does not confer jurisdiction." Interstate Petroleum Corp. v. Morgan, 249 F.3d 215, 221 n.7 (4th Cir. 2001); see also Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671 (1950) (explaining that, through the Declaratory Judgment Act, "Congress enlarged the range of remedies available in the federal courts but did not extend their jurisdiction").

Fed. R. Civ. P. 10(c), reveal indicia of final agency action as defined by Bennett. Moreover, plaintiff appears to concede as much, failing to address defendants' arguments regarding the APA in its response. Accordingly, the court finds that § 702 does not effect a waiver of defendants' sovereign immunity in this instance. See also Kentucky v. Graham, 473 U.S. 159, 166-67 (1985) ("[A]n official-capacity suit is, in all respects other than name, to be treated as a suit against the entity. . . . The only immunities that can be claimed in an official-capacity action are forms of sovereign immunity . . . .").

2) Federal Question Jurisdiction and the Medicare Act

The remaining alleged bases for the court's jurisdiction (28 U.S.C. §§ 1331, 42 U.S.C. §405(g), 1395ii, and 1395y(b)) may be analyzed together.

Section 405(g), as noted above, provides the basis for judicial review of the type of initial determination relevant here, that is, that Medicare would have a recovery claim against plaintiff under the MSP statute. See 42 U.S.C. § 1395ff; 42 C.F.R. § 405.924(b)(16); see also 42 U.S.C. 1395y(b)(2)(B)(vii) (directing the Secretary to "promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this subchapter for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan"). It provides that "[a]ny individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days . . . of notice of such decision." 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

"[Section] § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." See Heckler v. Ringer, 466 U.S. 602, 614-15 (1984)

(emphasis added) (footnote omitted); see also 42 U.S.C. 405(h) ("No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter."); Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 5 (2000) ("§ 405(h), as incorporated by § 1395ii, bars federal-question jurisdiction here."); McDonald v. Centra, Inc., 946 F.2d 1059, 1063 (4th Cir. 1991) (describing 42 U.S.C. § 405(h) as "bar[ring] jurisdiction" in certain circumstances).[5]

The Supreme Court has construed § 405(h) as "demand[ing] the 'channeling' of virtually all legal attacks through the [relevant] agency." See Ill. Council, 529 U.S. at 13. It has explained that § 405(h) "clearly appl[ies] in a typical Social Security or Medicare benefits case, where an individual seeks a monetary benefit from the agency (say, a disability payment, or payment for some medical procedure), the agency denies the benefit, and the individual challenges the lawfulness of that denial." Id. at 10. The Court's jurisprudence regarding § 405(g) and (h) "foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, . . . or the 'declaratory' versus 'injunctive' nature of the relief sought." Id. at 13. These types of challenges "may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions." Id. at 14.

[5] Plaintiff asserts that McDonald and its reliance upon Weinberger v. Salfi, 422 U.S. 749 (1975), upon which the Supreme Court's opinion Ringer also relied, have been derogated by later Supreme Court decisions. (See Pl.'s Resp (DE 13) at 16 n.6). But "both the district courts of this circuit and subsequent panels of th[e circuit] court are obliged to follow a decision of th[e circuit] court until it has been overruled by the Supreme Court or a decision by this court en banc." United States v. Henry, 11 F. App'x 350, 351 (4th Cir. 2001). Plaintiff does not contend that McDonald has been expressly overruled and does not contend that Ringer has been overruled in anyway. See generally Ill. Council, 529 U.S. at 18 ("[The] Court does not normally overturn, or so dramatically limit, earlier authority sub silentio."). Accordingly, the court treats each, and their attendant statements regarding § 405(h)'s jurisdictional cast, as binding.

The plain language of Illinois Council and § 405 preclude invocation of the court's federal question jurisdiction, see 28 U.S.C. § 1331, in this instance. Plaintiff does not contend and has not demonstrated that it has followed the procedures for administrative review of any initial determinations under § 405 as applicable here. Accordingly, the court does not have subject matter jurisdiction over plaintiff's claims under 28 U.S.C. § 1331 or 42 U.S.C. § 405. Further, §§ 1395ii and 1395y(b) do not create independent bases for jurisdiction by this court and, instead, refer to § 405 or the Secretary's regulations regarding appeals of certain determinations, respectively. See 42 U.S.C. § 1395ii, 1395y(b)(2)(B)(viii). In sum, jurisdiction by this court is precluded, or more accurately postponed, by the very statutes plaintiff cites for the court's alleged jurisdiction.

Plaintiff argues that this is the case recognized in Illinois Council where "§ 1395ii does not apply § 405(h)" because "application of § 405(h) would not simply channel review through the agency, but would mean no review at all." 529 U.S. at 19 (citing Bowen v. Mich. Acad. of Fam. Physicians, 476 U.S. 667 (1986)); see (Pl.'s Resp. (DE 13) at 10 (citing Mich. Acad., 476 U.S. at 680)). This exception is only applicable where "application of § 1395ii's channeling provision . . . will amount to the 'practical equivalent of a total denial of judicial review.'" Ill. Council, 529 U.S. at 20 (quoting McNary v. Haitian Refugee Ctr., Inc., 498 U.S. 479, 497 (1991)).

As described above, if plaintiff contests either a conditional payment reimbursement request or imposition of civil money penalty, avenues for eventual judicial review (either by a federal district court or court of appeals) exist. To the extent, plaintiff argues that review of civil money penalties is ephemeral because defendants' rule has not yet been finalized, so too is the possible imposition of a fine under that rule, pending its finalization. If defendants do, in fact, finalize a rule for imposition of civil money penalties that includes the practical equivalent of a

total denial of judicial review, plaintiff may challenge that as is appropriate, assuming compliance with other jurisdictional prerequisites.

Plaintiff asserts that "this action represent[s] precisely the kind of 'substantial statutory' challenge recognized by the Supreme Court as allowing for the exercise of federal question jurisdiction by the Court, notwithstanding the provisions of Section 405(h)." (Pl.'s Resp. (DE 13) at 10 (quoting Mich. Acad., 476 U.S. at 680)). But see Mich. Acad. 476 U.S. at 680 (discussing not merely claims of substantial statutory challenges but cases where there was otherwise "no review at all of substantial statutory and constitutional challenges" (emphasis added)). However, the Supreme Court held in Illinois Council that Michigan Academy stands for the proposition that "§ 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." Ill. Council, 529 U.S. at 19.

In Illinois Council, the Supreme Court explained that § 405(h) "plainly bars § 1331 review" in applicable cases "irrespective of whether the individual challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds." Id. at 10 (emphasis added). And even if the administrative agency fails to resolve a statutory question during its proceedings, "a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide." Id. at 23. Accordingly, nothing in Illinois Council's elucidation of the Michigan Academy exception to § 405(h) counsels expanding that exception to allow any statutory challenge to circumvent the relevant channeling provisions. See also id. at 13-14 (explaining that claims within the scope of § 405(h) "may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions"), 24 ("Proceeding through the agency . . . provides the agency

the opportunity to reconsider its policies, interpretations, and regulations in light of . . . challenges [to such].”).

Plaintiff further contends that while it “is aware of other cases decided by the Fourth Circuit and this Court construing the scope of Section 405(h) and requiring exhaustion of administrative remedies before judicial review,” those cases are ostensibly inapt because they “involved providers asserting claims for benefits under Medicare, and not an entity like the NCIGA.” (Pl.’s Resp. (DE 13) at 11). Yet, Illinois Council describes § 405(h) applying equally to “[c]laims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy.” Ill. Council, 529 U.S. at 14. Plaintiff is in the same shoes as the Illinois Council plaintiffs in that it understandably desires “advance knowledge for planning purposes” of the applicability or validity of certain Medicare requirements, but such individuals still are barred from relying on § 1331 over § 405(h)’s exclusive path for judicial review. See id. at 10, 16-17.

At its heart, plaintiff’s argument is that any postponed judicial review after administrative proceedings is unavailable to it because it, per its own contention, is not a primary plan or applicable plan within the meaning of the statutory framework. (See, e.g., Pl.’s Resp. (DE 13) at 10). This, of course, puts the cart before the horse given that the explicit purpose of plaintiff’s suit is a declaration by this court that “it is not a ‘primary plan’ or ‘applicable plan,’” (Compl. ¶ 1), that is, the merits of its claim. See generally Jones v. Am. Postal Workers Union, 192 F.3d 417, 422 (4th Cir. 1999) (“The existence of subject matter jurisdiction is a threshold issue, which this court must address before addressing the merits of [plaintiff’s statutory] claim.”). Further, its contention that § 405(h)’s channeling provision is inapplicable to it, (see, e.g., Pl.’s Resp. (DE 13) at 13), is belied by its invocation, inter alia, of 42 U.S.C. § 1395ii as a jurisdictional basis, when that section specifically incorporates “subsection[] . . . (h) . . . of section 405.”

At bottom, the court rejects plaintiff's contention that "[e]ntities . . . , which contend that they are not 'primary plans' as that term is defined in the MSP . . . are simply outside of the scope of these administrative review procedures and not subject to the jurisdictional bar of Section 405(h)." (Pl.s' Resp. (DE 13) at 15). Recognizing plaintiff's suggested exemption to § 405(h) would create an impermissible and easily invoked loophole to a process that the Supreme Court has described as "demand[ing] the 'channeling' of virtually all legal attacks through the [relevant] agency," including "disputes" as to "the application, interpretation, or constitutionality of interrelated regulations or statutory provisions." See Ill. Council, 529 U.S. at 13, 14; see also id. at 24 ("The fact that the agency might not provide a hearing for that particular contention, or may lack the power to provide one is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency.").[6] Nor does the court find the Ninth Circuit's statement that "[t]he district court had jurisdiction under 28 U.S.C. § 1331" in CIGA, without further analysis or discussion of the jurisdictional issue, helpful in the instant inquiry given that it appears the § 405(h) question was not considered. See 940 F.3d at 1066.

Finally, plaintiff argues that even if it was required to administratively exhaust its claims, certain historically accepted exceptions to administrative exhaustion requirements are applicable here. (See Pl.'s Resp. (DE 13) at 16 (citing McDonald v. Centra, 946 F.2d 1059 (4th Cir. 1991)). However, the Supreme Court has explained that "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'" and prevents application of "'ripeness' and 'exhaustion' exceptions." Ill. Council, 529 U.S. at 12.

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6 Contrary to plaintiff's contention, it is not "in the same position as the 'non-providers' before the D.C. Circuit in Council for Urological Interests," (Pl.'s Resp. (DE 13) at 9), who were able to invoke § 1331 jurisdiction because they had no other avenue for judicial review. See Council for Urological Ints. v. Sebelius, 668 F.3d 704, 714 (D.C. Cir. 2011). Unlike that case, any potential inapplicability of administrative review processes to the challenged conduct comes from plaintiff's own contention that it may not be regulated under this statute at all, in contrast with the uncontested acknowledgement by the government in Council for Urological Interests that those plaintiff "ha[d] no way to obtain review through Medicare Act channels." See id. at 708.

Accordingly, plaintiff may not rely traditional exhaustion-of-administrative-remedies exceptions to escape § 405(h)'s channeling requirement.

In sum, even presuming that plaintiff had demonstrated the injury-in-fact required for Article III jurisdiction, it has not shown that the court has the required congressionally granted jurisdiction to hear the instant claims. Therefore, they are also dismissed without prejudice for that reason as well.

CONCLUSION

Based on the foregoing, defendants' motion to dismiss is ALLOWED. Plaintiff's claims are DISMISSED WITHOUT PREJUDICE. The clerk is DIRECTED to close this case.

SO ORDERED, this the 21st day of September, 2021.

Louise W. Flanagan

LOUISE W. FLANAGAN
United States District Judge